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DEPARTMENT OF HEALTH & HUMAN SERVICES

**Public Health Service
Food and Drug Administration**

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94502
Telephone (510) 337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

June 26, 1997

Tzu-Ming Chen, President
Wo Lee Food Co.
208 Jackson Street
Oakland, CA 94607

WARNING LETTER

Dear Mr. Chen:

An inspection of your manufacturing facility on June 3, 4, 5, and 6, 1997, conducted by Food and Drug Administration Investigators Richard A. Martin and Frank A. Arezzo and Inspector Randall J. Plunkett, revealed significant insanitary conditions which may cause your products to be adulterated under the Food, Drug, and Cosmetic Act. Among the conditions noted during the inspection were:

- Live rats in four locations: inside bags of flour in the fortune cookie production area, among boxes of salted black beans in the warehouse area, in the hallway between the noodle area and the fortune cookie production area, and in the employee lunchroom.
- Live pigeons in the warehouse area and immediately outside a broken window which gave access to the fortune cookie production area.
- Live beetles in the noodle room and in the equipment storage room.
- Rodent gnawed bags of flour and evidence of rodent entry into the flour bags in two pallets of flour being held for use in fortune cookie production.
- Rodent excreta pellets throughout the entire facility.
- Rodent urine stains on rice bags and on boxes of black beans in the warehouse area, and on containers of flour and food packaging material in the fortune cookie production area.
- Numerous live flies in the fortune cookie room which landed on fortune cookie dough being held in open plastic buckets.

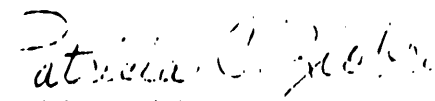
- Lavatory and hand washing facilities not readily available to production workers. The nearest toilet being used by the production workers was in the basement and had no hand washing sink.
- Numerous insanitary practices, including:
 - An employee was preparing vegetables while sitting on the floor, wearing dirty gloves, using a dirty knife, and using folded scrap cardboard as a cutting surface.
 - Cut fresh vegetables were put into cardboard boxes on the floor. The boxes were then stacked, with the bottom of the upper box resting directly on the vegetables in the lower box.
 - An employee picked up noodle dough that had fallen onto the floor and placed it into the hopper of the noodle making machine.

A food is adulterated within the meaning of Section 402(a)(3) of the Act if it consists in whole or in part of any filthy substance or is otherwise unfit for food. A food is adulterated within the meaning of Section 402(a)(4) of the Act if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated. Persons responsible for the adulteration of food may be enjoined under Section 302, and/or prosecuted under Section 301.

At the conclusion of the inspection, the insanitary conditions were listed on Form FDA 483 (Inspectional Observations) and discussed with you. A copy of this form is enclosed for your ready reference. This list is not meant to be an all-inclusive list of violations. It is your responsibility to ensure that all requirements of the Act and regulations promulgated thereunder are being met. Failure to achieve prompt corrective action may result in enforcement action without further notice.

Please advise us in writing within fifteen (15) working days of receipt of this letter about the measures you have taken to preclude adulteration of foods. Your response should be directed to Mr. Charles D. Hoffman, Compliance Officer.

Sincerely,


Patricia C. Ziobro
District Director

Enclosure: FDA 483